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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,067	WEINER ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5-10,13-25,27-30,32 and 34-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5-10,13-25,27-30,32 and 34-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response and amendments of 12/12/05 have been entered.

Claims 1, 11, 26, 31, and 33 are cancelled.

Claims 5, 9, 13, 18, 19, 23-25, 29, 30, 32, and 34 are amended.

Claims 35-39 are newly presented.

Claims 2, 5-10, 13-25, 27-30, 32, and 34-39 are pending and considered.

Note: Change in Art Unit and SPE

The Examiner has been reassigned to Art Unit 1633. Therefore, future correspondence should reflect such changes. Also, at the end of the Action is the information regarding the SPE of the Art Unit.

Claim Objections

Claims 2 and 32 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 depends from Claim 5, but expands on the method of administration to include new methods of administration not included in Claim 5. Claim 32 depends from Claim 5, but limits the method of administration to intramuscular injection, to which Claim 5 is already limited.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 32 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112 – indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In light of Applicant's argument and amendments and claim cancellations, the rejections of claims 9-17 under 35 USC 112, second paragraph, for being indefinite, are alternatively withdrawn, or rendered moot, and thus are withdrawn.

Claim Rejections – 35 USC 112, first paragraph – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of Applicant's amendment and argument, the rejections of Claims 2, 5-10, 13-25, 27-30, 32, and 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons set forth in the prior Official Actions, are withdrawn. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

35 USC 112, first paragraph – Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2, 5-10, 13-25, 27-30, 32, and 34-39 remain and/or are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

(1) A method of delivering a protein to a macrophage cell of an individual, comprising:

Administering to said individual at a site on said individual's body, a DNA vector comprising a sequence encoding said protein, operably linked to a promoter selected from the group consisting of a CD156 promoter, a M-CSFR promoter, and a Fc-gamma-RI promoter, and a polyadenylation signal that is functional in a macrophage cell,

wherein said DNA vector is taken up by a macrophage cell and said sequence is expressed to produce said protein in said macrophage cell;

(2) A method of delivering a protein to a macrophage cell of an individual, comprising:

administering to said individual by intramuscular injection, a DNA vector comprising a nucleotide sequence that encodes said protein, wherein said DNA molecule is operably linked to a macrophage-specific promoter and a polyadenylation signal that is functional in a macrophage cell, wherein said promoter is selected from the group consisting of a CD156 promoter, a M-CSFR promoter, and a Fc-gamma-RI promoter, wherein said DNA molecule is taken up by a macrophage cell and said sequence is expressed to produce said protein in said macrophage cell;

(3) A method of delivering a protein to a lymphnode of an individual, comprising:

indentifying the lymphnode to which protein is to be delivered;

locating a site proximal to said lymphnode;

administering to said individual at said site, a DNA vector comprising a nucleotide a sequence encoding said protein, operably linked to a secretion signal, promoter selected from the group consisting of a CD156 promoter, a M-CSFR promoter, and a Fc-gamma-RI promoter, and a polyadenylation signal that is functional in a macrophage cell,

wherein said DNA vector is taken up by a macrophage cell proximal to said lymphnode, the nucleotide sequence is expressed in such macrophage, and said macrophage drains to said lymphnode, thereby delivering the protein to said lymphnode;

(4) A method of delivering a desired protein to an individual, comprising:

administering to said individual a DNA vector comprising a nucleotide sequence that encodes said protein, operably linked to a promoter selected from the group consisting of a CD156 promoter, a M-CSFR promoter, and a Fc-gamma-RI promoter, and a polyadenylation signal that is functional in a macrophage cell, wherein said DNA vector is taken up by a macrophage cell and expressed to produce said protein in said macrophage cell,

does not reasonably provide enablement for any macrophage-specific promoter derived from a human gene, a catalase promoter, a p73 promoter, or the delivery of proteins to the lymphnode where the protein is not linked to a secretion signal.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 18-25 and 27-30 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is noted that Applicant has amended the claims to only include plasmid injections, and hence, such rejections have been withdrawn for encompassing all DNA vectors. Further, Applicant's amendments to the claims for lymph node delivery have been limited to lymph nodes proximal to the site of injection, and hence, the enablement on that basis is also withdrawn.

Response to Argument – Enablement

Applicant's arguments of 12/12/05 have been considered but are not found relevant in light of the new reasoning provided above.

Applicant argues that references to catalase promoters and p73 promoters have been deleted (Applicant's argument of 12/12/05, p. 16, paragraph 4).

Such is not persuasive. The claims have not been so amended.

Applicant argues that the claims are enabled for all macrophage specific promoters, arguing that there exists no evidence that any macrophage-specific promoter would function in the claimed methods (Applicant's argument of 12/12/05, p. 17, paragraph 1).

Such is not persuasive. First, Applicant appears to be arguing cancelled claims, e.g., Claim 1. Moreover, the Examiner has demonstrated that specifically-claimed promoters are not macrophage specific (e.g., Official Action of 6/20/05, pp. 15-16, paragraphs bridging). Lastly, the Examiner interprets the claims that broadly claim macrophage specific promoters derived from human genes to encompass any macrophage specific promoter made from any human gene, even if such gene did not comprise a macrophage specific promoter (Official Action of 6/20/05, p. 11, last paragraph), and the method of deriving such promoters is not reasonably predictable (e.g., Id., p. 15, paragraph 2).

Applicant argues that the Examiner has not supplied any evidence that proteins not linked to secretion signals would not be secreted and released to the lymphnode (Applicant's argument of 12/12/05, p. 17, paragraph 2).

Such is not persuasive. At some point the Examiner has to take science to be understood by the Artisan, otherwise the Examiner would have to reproduce all of science within each and every official action. However, to demonstrate the implied argument that the Examiner is simply arguing random possibility is incorrect, Sakaguchi (1997) Curr. Opin. Biotechnol., 8: 595-601 teaches that secreted proteins require a secretion signal, and in the absence of a secretion signal are expressed only *in vivo* (p. 595, col. 2).

Applicant argues that the claims to inducing immune responses, modulating the immune system and eliminating cells of the lymphnode, each in an individual, are not gene therapy, and hence, the Examiner has incorrectly applied the art (Applicant's argument of 12/12/05, p. 17, paragraph 5).

Such is not perasuasive. Applicant's claims still have to overcome all the same aspects of gene targeting and expression for a long enough period of time to effect the specific immune induction/modulation/lymphnode killing that is encompassed. The Examiner fails to understand why these methods are not subject to the same problems. To wit, call it what you will, the Examiner believes the art cited to be among the closest related Art to Applicant's claimed invention.

Applicant argues that the art cited by the Examiner is overcome by the specific working examples of the specification, and hence, the Art does not apply (Applicant's argument of 12/12/05, p. 18, paragraph 1).

Such is not persuasive. As has been analyzed, the Examiner has shown that Applicant's examples comprise specific constructs which are not using the promoters of the invention, and hence, the effects may be due to other cells being effected, rather than

the macrophages (Official Action of 6/20/05, p. 21, paragraph 2); the promoters are not all macrophage-specific (e.g., catalase and p73, Id., pp. 20-21, paragraph bridging); secretory signals are required for secretion (e.g., Id., p. 15, paragraph 2); the macrophage cells may be eliminated before any destruction of the lymphnode (e.g., Id., pp. 16-17, paragraph bridging); and the mechanisms of modulation are so broad and complex that the Artisan could not reasonably predict how to modulate the modulate the immune system in any particular manner (e.g., Id., p. 17, paragraph 2). Moreover, Applicant's examples do not provide any evidence to overcome these problems (e.g., Id., pp. 20-21).

Applicant argues that the in absence of evidence to the contrary, the claimed invention is enabled, due to the working examples (Applicant's argument of 12/12/05, p. 18, last paragraph).

Such is not perasuasive. The same reasoning as provided in the last answer are applied. Moreover, to reemphasize, while specific effects of the immune system were noted to occur, Applicants claimed methods are so broad as to not be enabled, because no modulation is reasonably predictable, only specific effects. Even Applicant's specification recognizes that the mechanisms of the immune system are still not fully understood, and hence, it is clear that the modulation of the immune system, particularly given its full breadth, is not enabled (e.g., Official Action of 6/20/05, p. 17, paragraph 2; e.g., SPECIFICATION, p. 35, paragraph 2).

Applicant argues that the gene therapy references only have to do with sustained expression, but such is not required in the instant Application, which is drawn to delivery of protein (Applicant's argument of 12/12/05, p. 19, paragraph 1).

Such is not persuasive. Certain claims have to protein delivery, e.g., Claim 1, and these claims are facing a scope of enablement. Other claims have to do with inducing an immune response (Claim 18), modulating the immune system (Claim 23), and eliminating cells of the lymphnode (Claim 25). These claim sets do require sufficient targeting and expression, and hence, the art is applied properly.

Applicant argues that the Examiner uses US Pat Pub No. 2004/0224404 to argue that the macrophage is not easily transduced, and such ignores Applicant's examples which overcomes the problems (Applicant's argument of 12/12/05, p. 19, paragraph 2).

Such is not persuasive. Applicant's argument is noted, but not deemed persuasive, as Applicant's claims are now limited to plasmid vectors.

Applicant argues that the catalase promoter and p73 promoter are enabled, and the Examiner has supplied no art to demonstrate these promoters are not specifically expressed in macrophages, and further requesting an affidavit (Applicant's argument of 12/12/05, pp. 19-20, paragraph bridging).

Such is not persuasive. The Examiner supplied such art (Official Action of 6/20/05, pp. 15-16, paragraph bridging). The Examiner will also provide an affidavit if Applicant still wishes one.

Applicant argues that the Examiner provides no "reasonable evidence" that would cause the Artisan to doubt the truth of the claimed invention as supported by the specification and art (Applicant's argument of 12/12/05, p. 20, paragraph 2).

Such is not persuasive. As rebutted above, the Examiner believes the evidence is that the Artisan would doubt the truth of the claimed invention, even in light of Applicant's disclosure.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

In light of the amendments of Claims 2 and 32, and further cancellation of claim 1, the rejections of such claims under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0063652 to Jolly, filed 3/29/01, and claiming priority to at least 11/25/97, are rendered moot and thus are withdrawn.

Claim 29 remains rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0063652 to Jolly, filed 3/29/01, and claiming priority to at least 11/25/97, for reasons of record.

Response to Argument – anticipation, Jolly

Applicant's argument of 12/12/05 has been fully considered but is not found persuasive.

Applicant argues that Claim 29 has been cancelled (Applicant's argument of 12/12/05, p. 20, paragraph 4).

Such is not persuasive. Applicant's amended claims include Claim 29. The amendments do not remove the claim from the same rejection. The rejection held.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

While the rejections of claims 5, 7-8, 17, and 22 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0063652 to Jolly, filed 3/29/01, and claiming priority to at least 11/25/97 and Kataoka, et al. (1997) J. Biol. Chem., 272(29): 18209-15, are rendered moot by the amendments,

Claims 1, 5, 7, 8, 17, 32, and 35 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0063652 to Jolly, filed 3/29/01, and claiming priority to at least 11/25/97 and Ross, et al. (1998) J. Biol. Chem., 273(12): 6662-69, for reasons necessitated by the amendments.

Jolly, in addition to teaching the use of plasmids encoding HSV-tk (see 35 USC 102(e) rejection, above), also teaches the administration of blocking proteins to block pathogenic interactions, which may be in secretable form (paragraph 0155) to block pathogenic interactions local to the cell (Id.). Hence, Jolly is inherently teaching the use of secretion signals, as such is the mechanism in which proteins are secreted. Moreover, such compositions may be administered with bupivacaine, which helps with the transfection of the cells (paragraph 0365). However, Jolly does not teach the specific promoters claimed.

On the other hand, Ross teaches that the RcgammaRI and M-CSFR genes each have promoters which are macrophage-specific (e.g., col. 2, paragraph 2).

Therefore, at the time of invention by Applicant, it would have been obvious to modify the invention of Jolly, by using the M-CSFR or RcgammaRI human gene promoters. The Artisan would have been motivated to do so because the promoters are specific for macrophages of humans, as is taught to be desired by Jolly. Moreover, the Artisan would have had a reasonable expectation of success, as Jolly had already demonstrated the methods, and Ross had demonstrated that the promoters are specific for macrophages.

While the previous rejection of Claim 6 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0063652 to Jolly, filed 3/29/01, and claiming priority to at least 11/25/97 and Ross, et al. (1998) J. Biol. Chem., 273(12): 6662-69 as applied to claim 5 above, and further in view of U.S. Patent No. 5,763,416 to Bonadio, et al., filed 2/18/94 and Patented 6/9/98, is withdrawn,

Claim 6 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0063652 to Jolly, filed 3/29/01, and claiming priority to at least 11/25/97 and Kataoka, et al. (1997) J. Biol. Chem., 272(29): 18209-15 as applied to claim 5 above, and further in view of U.S. Patent No. 5,763,416 to Bonadio, et al., filed 2/18/94 and Patented 6/9/98.

As shown above, the Jolly reference and Ross reference obviate the base claim, claim 5, however they do not teach or suggest the use of the SV40 polyA signal.

On the other hand, Bonadio teaches that the SV40 polyA signal is a standard polyA signal for termination of transcripts (e.g., EXAMPLE IX).

Hence, at the time of invention by Applicant, it would have been obvious the methods of Jolly and Kataoka with the polyA signal as taught by Bonadio. The Artisan would have been motivated to do so because such promoter was known in the art to terminate transcription. Moreover, the Artisan would have had a reasonable expectation of success, as Bonadio had previously shown such polyA sequence to be able to terminate transcription, confirming what was well known in the Art.

Note to Applicant

Should Applicant overcome the rejections based on lack of enablement for inducing an immune response, for modulating the immune system, and for eliminating cells of the lymphnode, Applicant should note that rejections based on U.S. Patent Application Publication No. 2004/0063652 may be subsequently applied, as this reference does describe the use of vectors for inducing immune responses with genes driven by macrophage-specific promoters, as discussed in the art rejections above. Moreover, the Examiner, in light of U.S. Patent No. 5,783,567, which teaches that the macrophages drain into the lymphnodes (col. 8, paragraph 3), considers this aspect inherent in the methods of Jolly. However, the Examiner has failed to find any art of record that would indicate the targeting of specific lymphnodes local to a site of administration for delivery of proteins by macrophages.

Response to Argument – cited art

Applicant argues that the Examiner is performing piecemeal rejections of Applicant's claims by citing the above-listed art (Applicant's argument of 12/12/05, p. 21, paragraph 2).

Such is not persuasive. The Examiner has made clear that such art is not applied because Applicant's claims are not found enabled; however, in order to assist Applicant in compact prosecution and expedite issuance of any claims which are found patentable, the Examiner has supplied art that Applicant is requested to consider if they feel that the claims are enabled, thereby allowing Applicant to draft claim to overcome prior art issues that may be relevant to Applicant's claimed subject matter. More specifically, the art is cited because it provides similar guidance as Applicant's specification, and would anticipate the claimed invention.

CONCLUSION

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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